IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Michael P. WALLACE** **Serial No.: 10/669,543** **Filed:** September 23, 2003 **For:** EXTERNAL ACTIVATION OF VASO-OCCLUSIVE IMPLANTS	**Group Art Unit:** 3734 **Confirmation No.:** 4647 **Examiner:** Diane D. Yabut

APPEAL BRIEF-CFR 41.37

M/S: Board of Patent Appeals and Interferences
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is being filed in furtherance of the Notice of Appeal, filed October 27, 2009. It contains the following items in the order indicated below, as required by C.F.R. §41.37:

I. Real Party in Interest
II. Related Appeals and Interferences
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I. Real Party in Interest

The real party in interest in this appeal is Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.), a corporation organized under the laws of Minnesota.

II. Related Appeals and Interferences

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. Status of Claims

This application includes pending claims1-6, 10-11, 13-16 and 18. Claim 1-6, 10-11, 13-16 and 18 stand rejected. Claims 7-9, 12, 17 and 19-22 are cancelled, leaving no claims allowed. The claims on appeal are claims 1-6, 10-11, 13-16 and 18.

IV. Status of Amendments

All amendments have been entered.

V. Summary of Claimed Subject Matter

Although the invention should not be limited to the preferred embodiments described in the specification, the invention will now be described in terms of certain embodiments in order to aid in understanding the invention.

Independent claim 1 is directed to a method for embolizing a target site in a vasculature of a body (page 3, lines 2-9, page 13, line 18 to page 20, line 18, Figs. 3A-C). The method comprises, detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device at a target site in a vasculature of a body (page 14, lines 10-13, Figs. 3A-B), said vaso-occlusive device comprising a therapeutic bioactive agent coating and a polymeric material coating substantially covering the

bioactive agent coating (page 13, lines 20-23); and delivering energy from an energy emitting element located outside the body to thereby heat the vaso-occlusive device at the target site (page 3, lines 2-9, page 15, lines 4-7, Fig. 3C), wherein the polymeric material at least partially melts or softens so that the bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated (page 3, lines 2-9, page 15, line 21 to page 16, line 6, Fig. 3C).

Independent claim 10 is directed to a method for embolizing a target site in a body (page 3, lines 2-9, page 13, line 18 to page 20, line 18, Figs. 3A-C). The method comprises detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device at a target site in a body (page 14, lines 10-13, Figs. 3A-B), positioning the body in a magnetic resonance imaging ("MRI") device (page 6, line 6, page 15, lines 7-11), and activating the MRI device to apply a variable magnetic field to the body, thereby heating a highly resistive element in the vaso-occlusive device (page 3, lines 2-9, page 15, lines 4-7, 10-20, Fig. 3C) and at least partially melting or softening a polymeric material exterior coating on the vaso-occlusive device to thereby release or activate an underlying therapeutic bioactive agent (page 3, lines 2-9, page 15, line 21 to page 16, line 6, Fig. 3C).

Independent claim 14 is directed to a method for embolizing a target site in a body (page 3, lines 2-9, page 13, line 18 to page 20, line 18, Figs. 3A-C). The method comprises detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device in an aneurysm (page 14, lines 10-13, Figs. 3A-B), the device including a highly conductive coil forming a lumen (page 6, lines 7-9, page 17, lines 9 and 20, page 18, line 3, Figs. 2A, and 4A-B), a highly resistive element at least partially disposed in the lumen (page 17, lines 20-21, page 18, lines 5-6, Figs. 4A-B); a therapeutic

bioactive agent coating of the coil and a polymeric material coating substantially covering the bioactive agent coating (page 9, line 11, line 22 to page 11 line 12, page 13, lines 21-23); and applying magnetic field energy to the device from an energy emitting element located outside of the body, thereby heating the highly resistive element (page 3, lines 2-9, page 15, lines 4-7, 10-20, Fig. 3C) and, by way of convective heat transfer from the highly resistive element, heating the coil thereby at least partially melting or softening the polymeric material and releasing or activating the bioactive agent (page 3, lines 2-9, line 22 to page 4, line 2, page 12, line 11, page 15, line 4-7, line 21 to page 16, line 6, Fig. 3C).

VI. Grounds of Rejection to be Reviewed on Appeal

A) Whether claims 1-2 and 6 are unpatentable under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,397,107 ("Lee") in view of U.S. Patent No. 5,749,894 ("Engelson"), and in further view of U.S. Patent No. 5,824,049 ("Ragheb").

B) Whether claims 3-4, 10-11 and 13 are unpatentable under 35 U.S.C. §103(a) as being obvious over Lee, in view of Engelson and Ragheb, and in further view of U.S. Pub. 2004/0215124 ("Yamasaki").

C) Whether claim 5 is unpatentable under 35 U.S.C. §103(a) as being obvious over Lee in view of Engelson and Ragheb, as applied to claims 1 and 19, and in still further view of U.S. Patent No. 6,740,094 ("Maitland").

D) Whether claims 14-16 and 18 are unpatentable under 35 U.S.C. §103(a) as being obvious over Lee, in view of Engelson and Ragheb, and in still further view of U.S. Patent No. 5,853,418 ("Ken").

VII. Arguments

Legal standards

The Supreme Court set forth the basic test for obviousness in Graham v. John Deere, 383 U.S. 1, 148 (1966). Additionally, the Supreme Court has addressed the issue of obviousness in KSR International vs. Teleflex Inc., 127 S. Ct. 1727 (2007), in which the Court reiterated the requirement that a rejection on "obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness", and further that a "fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex parte reasoning". Further, the Supreme Court in KSR, stated: "A patent composed of several elements is not proven obvious merely by demonstrating that each element was, independently, known in the prior art...it can be important to identified a reason that would have prompted a person of ordinary skill in the relevant field to combined the elements in the way the claimed new invention does".

Additionally, in Ex parte WHALEN, the BPAI reversed an Examiner's claim rejections based on obviousness, since the Examiner had not set forth "an adequate basis – based on evidence or scientific reasoning" to support the rejections. This BPAI cited the Supreme Court decision in KSR, and agreed that "obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some 'apparent reason to combine the known elements in the fashion claimed" (Ex parte Whalen, citing KSR at 1741).

While not specifically addressed by the Supreme Court in KSR, for a combination of prior art references to render a claimed device obvious, a device resulting from the

combination of prior art references must still consider **all** of the limitations of that claim (See MPEP §2143). Also, a "prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP §2141.03 (VI.). "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." MPEP §2143.02 (VI.).

The above analyses should be applied to determine whether or not the cited references render the appealed claims obvious. For the reasons that follow, Appellants respectfully submit the appealed claims are not obvious in view of the cited references.

A) Rejection of claims 1-2 and 6 under 35 U.S.C. §103(a) over Lee in view of Engelson and in further view of Ragheb

Independent claim 1 recites a method for embolizing a target site in a vasculature of a body, including detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device at a target site in a vasculature of a body, the vaso-occlusive device comprising a therapeutic bioactive agent coating and a polymeric material coating substantially covering the bioactive agent coating; and delivering energy from an energy emitting element located outside the body to thereby heat the vaso-occlusive device at the target site, wherein the polymeric material at least partially melts or softens so that the bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated.

Conversely, Lee discloses delivering high frequency energy from outside the body to heat an implanted occlusive device in order to heat and cause the surrounding

tissue to coagulate and contract around the device. (Col. 2, lines 50-65). There is no disclosure or suggestion in Lee that the vaso-occlusive device comprises a therapeutic bioactive agent coating or a polymeric material coating substantially covering a bioactive agent coating. Nor is there any disclosure or suggestion in Lee that heating the vaso-occlusive device at least partially melts or softens a polymeric material so that a bioactive agent is released or activated at the treatment site. Nor do Engelson or Ragheb disclose or suggest these missing claim limitations.

Engelson discloses deploying a vaso-occlusive device that is heated preferably by a light-emitting device inside the blood vessel in order to reform or melt a polymer coating over the device that adheres to and stabilizes the vaso-occlusive device. (Col. 1, lines 15-20, Col. 3, line 64 to Col. 4, line 55, Col. 5, lines 5-17, Col. 9, lines 31-41). Again, there is no disclosure or suggestion in Engelson that a therapeutic bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated.

According to the Final Office Action, "the examiner refers to the device of Raghreb [for] advantageously using releasable bioactive materials..." (page 8, preposition in brackets added). Appellants respectfully submit that the above quoted statement disregards key aspects of the actual disclosures of the references being combined and does not support a prima facie case of obviousness.

Ragheb discloses a coated medical implant (i.e. stent) having a layer of a bioactive material (preferably an antithrombotic or anticoagulant agent, such as heparin), covered with a porous layer of a biocompatible polymer that allows a controlled release of the bioactive material (Col. 3, lines 9-65). "The purpose of the porous layer 20 is to provide a controlled released of the bioactive material when the

device 10 is positioned in the vascular system of a patient" (Col. 10, lines 31-38). Ragheb discloses that the device is particularly used in percutaneous transluminal angioplasty to avoid abrupt closure and/or restenosis of a blood vessel by having controlled release of anticoagulants. (Col. 5, lines 47-64). Again, there is no disclosure or suggestion in Ragheb that a therapeutic bioactive agent is released or activated at the treatment site when the medical implant is heated.

Additionally, the Final Office Action erroneously states that "the claims do not recite that the bioactive agent is only released or activated until after the vaso-occlusive device is heated, but rather that heating the vaso-occlusive device melts the polymeric material and releases the bioactive agent specifically at the treatment site" (page 9).

Appellant respectfully disagrees. Claim 1 specifically requires that the bioactive agent is released or activated as consequence of the melting or softening or the polymeric material: "...delivering energy from an energy emitting element located outside the body to thereby heat the vaso-occlusive device at the target site, wherein the polymeric material at least partially melts or softens so that the bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated" (Emphasis added).

Furthermore, the above quoted statement of page 9 of the Final Office Action contradicts a previous statement of the Final Office Action: "It would have been obvious.... to cover a bioactive agent coating with a polymeric material coating, as taught by Ragheb et al, to protect the bioactive agent coating from being released until desired...." (Page 4).

There is no reason set forth in the record based on evidence or scientific reasoning, and the Final Office Action fails to provide any, that a person skilled in the art

at the time of filing the present application would have prompted to combine the teachings of the three cited references to achieve the method of claim 1.

Furthermore, while Appellant does not concede that there is a reason to combine these references, even if a person skilled in the art were to combine the teachings of Lee, Engelson and Ragheb, the resulting method would include deploying a vaso-occlusive device at a target site, the device having a coating of a porous polymeric material and a coating of bioactive anticoagulant agent (Ragheb), and delivering energy from a high frequency energy located outside the body (Lee) to thereby heat the vaso-occlusive device at the target site to reform or melt the polymeric coating and stabilize the vaso-occlusive device (Engelson). The bioactive agent would be released due to the porous polymeric coating, as disclosed in Ragheb, prior to heating the device. Thus, the bioactive agent would not be released or activated when the vaso-occlusive device is heated. Therefore, such combination will not produce the claimed method of embolizing a target site in a vasculature of a body, wherein a therapeutic bioactive agent underlying a polymeric material coating is released or activated at the treatment site when the vaso-occlusive device is heated by delivering energy from an energy emitting element located outside the body to thereby melt or at least partially soften the polymeric material.

For at least the foregoing reasons, Appellant respectfully submits that the Examiner has not set forth a prima facie case that independent claim 1, and its respective dependent claims 2 and 6, are unpatentable under 35 U.S.C. §103, as being obvious over Lee, in view of Engelson and in further view of Ragheb.

B) Rejection of claims 3-4, 10-11 and 13 under 35 U.S.C. §103(a) over Lee in view of Engelson, in view of Ragheb, and in further view of Yamasaki

The Final Office Action states that the combination of Lee, Engelson and Ragheb disclose the claimed invention, except having a magnetic resonance imaging (MRI) device to apply a magnetic field. Hence, Yamasaki is thrown into the mix. Appellant respectfully disagrees.

As discussed above, the combination of Lee, Engelson and Ragheb does not disclose or suggest all of the limitations of independent claim 1, and such combination does not disclose or suggest the all the limitations of independent claim 10 for the same reasons. In particular, the combination of Lee, Engelson and Ragheb does not disclose the acts of "heating a highly resistive element in the vaso-occlusive device and at least partially melting or softening a polymeric material exterior coating on the vaso-occlusive device to thereby release or activate an underlying therapeutic bioactive agent." Nor does Yamasaki teach or suggest these missing claim limitations.

Yamasaki discloses introducing an irritant in serum form into the aneurysm, causing the aneurysm to shrink *"over the course of several days or weeks"* (Yamasaki, paragraph 62 - 66). Although, MRI may be used to cure the irritant in Yamasaki, a method combining Lee, Engelson, Ragheb with Yamasaki, would not yield each and every limitation of respective claims 3-4, 10-11 and 13.

In particular, Examiner has not set forth any reason based on evidence or scientific reasoning the one skilled in the art would be prompted to modify Engelson's method using a a light-emitting device to instead use magnetic field in order to reform the polymers or to release or activate therapeutic bioactive agents.

Regarding claim 4, the office action states (on pages 5 and 6) that "it would have

been obvious… to provide a vaso-occlusion device comprising a ferrous material that responds to applied energy so that the device remains cohesive… and therefore properly treating the target site." However, there is no mention in claim 4 of the ferrous material causing the device to be (or remain) "cohesive."

Regarding claim 11, which recites that the heating of the device causes coagulation of the blood, Ragheb repeatedly discloses anticoagulants (i.e. heparin) as the bioactive material coating and avoiding abrupt closure and/or restenosis of a blood vessel.

For at least these reasons, Appellant respectfully submits that the Examiner has not set forth a prima facie case that independent claim 10, and dependent claims 3-4, 11 and 13, are unpatentable under 35 U.S.C. §103, as being obvious over Lee, in view of Engelson and Ragheb and in still further view of Yamasaki.

C) Rejection of claim 5 under 35 U.S.C. §103(a) over Lee in view of Engelson, in view of Ragheb, and in further view of Maitland

Maitland discloses the activation and expansion of a shape memory actuator when heated to remove blockages in a blood vessel, wherein the energy delivered to the actuator may be ultrasounds waves (Col 6, lines 26-57). However, Lee, Engelson and Ragheb do not disclose all of the limitations of independent claim 1, as discussed above, and having an energy source comprising an ultrasound device, as disclosed in Maitland, does not provide the missing claim limitations.

For at least these reasons, Appellant respectfully submits that the Examiner has not set forth a prima facie case that claim 5 is unpatentable under 35 U.S.C. §103, as

being obvious over Lee, in view of Engelson, and Ragheb, and in still further view of Maitland.

D) Rejection of claims 14-16 and 18 under 35 U.S.C. §103(a) over Lee in view of Engelson, in view of Ragheb, and in further view of Ken

As discussed above, the combination of Lee, Engelson and Ragheb does not disclose or suggest all of the limitations of independent claims 1 or 10, nor does their combination disclose or suggest the limitations of independent claim 14, for at least the same reasons. In particular, the combination of Lee, Engelson and Ragheb does not disclose the acts of "heating the highly resistive element and, by way of convective heat transfer from the highly resistive element, heating the coil thereby at least partially melting or softening the polymeric material and releasing or activating the bioactive agent." Nor does Ken teach or suggest these missing claim limitations.

Ken discloses a stretch-resisting member for a vaso-occlusive coil device that may "optionally contain modest amounts of iron." (Col. 5, lines 1-2). However, there is no disclosure or suggestion in Ken that such "modest amounts of iron" in the stretch-resisting filament are provided in adequate concentration to cause the stretch-resisting filament to act as a heating member if exposed to energy transmitted by external energy emitting element after detachment of the coil, as required by independent claim 14. Ken discloses releasing a vaso-occlusive coil in a treatment site using a well-known electrolytically severable joint (Col 6, lines 38-62), which is different than heating the already detached and implanted coil by application of energy transmitted by an energy emitting element located external to the patient. Certainly, Ken does not suggest the use of magnetic field to heat the device or otherwise be desirable.

The Final Office Action states that "...the "modest amounts of iron" disclosed in Ken does not necessarily mean that the device possesses insufficient concentration of iron to cause heating in response to magnetic energy" (page 10). However, according to the MPEP 2112, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. The examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

Applicant respectfully indicates that the Final Office Action quote of page 10 does not provide an articulated reasoning with some rational underpinning to support the legal conclusion of inherency or obviousness, since there is nothing in the disclosure of Ken to support that the stretch-resisting filament would act as a heating member.

Claim 16 recites the heating of the device to cause blood coagulation, which teaches away at least from the disclosure of Ragheb, which repeatedly discloses anticoagulants (i.e. heparin) as the bioactive material coating and avoiding abrupt closure and/or restenosis of a blood vessel.

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For at least these reasons, Appellant respectfully submits that the Examiner has not set forth a prima facie case that claim 14, and its dependent claims 15, 16 and 18 are unpatentable under 35 U.S.C. §103, as being obvious over Lee, in view of Engelson and Ragheb, and in still further view of Ken.

Respectfully submitted,
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Dated: December 23, 2009

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VIII. Claims Appendix

1. A method for embolizing a target site in a vasculature of a body, comprising:

detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device at a target site in a vasculature of a body, said vaso-occlusive device comprising a therapeutic bioactive agent coating and a polymeric material coating substantially covering the bioactive agent coating; and

delivering energy from an energy emitting element located outside the body to thereby heat the vaso-occlusive device at the target site, wherein the polymeric material at least partially melts or softens so that the bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated.

2. The method of claim 1, the target site comprising one of an aneurysm, a blood vessel lumen and a fistula.

3. The method of claim 1, the energy emitting element comprising a magnetic resonance device.

4. The method of claim 3, the vaso-occlusive device comprising a ferrous material in sufficient concentration to cause heating of the device in response to energy delivered by the magnetic resonance device.

5. The method of claim 1, the energy emitting element comprising an ultrasound device acoustically coupled to an exterior of the body.

6. The method of claim 1, the energy emitting element comprising a radio frequency device.

10. A method for embolizing a target site in a body, comprising:

detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device at a target site in a body;

positioning the body in a magnetic resonance imaging ("MRI") device; and

activating the MRI device to apply a variable magnetic field to the body, thereby heating a highly resistive element in the vaso-occlusive device and at least partially melting or softening a polymeric material exterior coating on the vaso-occlusive device to thereby release or activate an underlying therapeutic bioactive agent.

11. The method of claim 10, wherein the vaso-occlusive device is sufficiently heated by application of magnetic field energy to cause coagulation of blood at the target site.

13. The method of claim 10, wherein the vaso-occlusive device is deployed at the target site in a three-dimensional shape and sufficiently heated by application of magnetic field energy to at least partially melt and fuse together portions thereof to stabilize the vaso-occlusive device in the three-dimensional shape.

14. A method for embolizing an aneurysm in a body, comprising:

detaching a vaso-occlusive device from a delivery catheter to thereby deploy the

vaso-occlusive device in an aneurysm, the device including

a highly conductive coil forming a lumen,

a highly resistive element at least partially disposed in the lumen;

a therapeutic bioactive agent coating of the coil and a polymeric material coating substantially covering the bioactive agent coating; and

applying magnetic field energy to the device from an energy emitting element located outside of the body, thereby heating the highly resistive element and, by way of convective heat transfer from the highly resistive element, heating the coil thereby at least partially melting or softening the polymeric material and releasing or activating the bioactive agent.

15. The method of claim 14, the coil comprising platinum; the highly resistive element comprising ferrous material.

16. The method of claim 14, wherein the coil is sufficiently heated to cause blood coagulation in the aneurysm.

18. The method of claim 14, wherein the coil is deployed in the aneurysm in a three-dimensional shape and sufficiently heated to at least partially melt and fuse together portions thereof to stabilize the coil in the three-dimensional shape.

IX. Evidence Appendix

A. U.S. Patent No. 6,397,107; originally cited by the Examiner in the Office Action, dated February 20, 2008.

B. U.S. Patent No. 5,749,894; originally cited by the Examiner in the Office Action, dated December 18, 2006.

C. U.S. Patent No. 5,824,049; originally cited by the Examiner in the Office Action, dated January 9, 2009.

D. U.S. Patent Publication No. 2004/0215124; originally cited by the Examiner in the Office Action, dated December 18, 2006.

E. U.S. Patent No. 6,740,094; originally cited by the Examiner in the Office Action, dated December 18, 2006.

F. U.S. Patent No. 5,853,418; originally cited by the Examiner in the Office Action, dated December 18, 2006.

X. Related Proceedings Appendix

None.